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Katja Richter

Katja Richter is the CEO and founder of *Heppe Medical Chitosan GmbH* (HMC), a German company specializing in chitosan and chitosan derivatives for biomedical, pharmaceutical and medical device applications. She has more than 20 years of experience in chitosan technology, industrial scale-up, quality management and regulatory requirements. She studied biotechnology at the Technical University of Braunschweig, Germany, where her focus was on chitosan-based drug delivery systems. Her work focuses on translating chitosan-based concepts from research into reproducible, specification-compliant materials and manufacturing processes. She has extensive experience in material characterization, process development, quality-by-design and regulatory aspects related to ISO 13485 and GMP environments.

In addition to her company, she has been on the Board of EUCHIS (European Chitin Society) since 2009 and treasurer of the society since 2017. Since 2022 she is a board member and treasurer of the association for pharmaceutical companies "Life Science Cluster Saxony Anhalt" in Germany. Katja Richter is also a member of EPNOE (European polysaccharide network of excellence) and member of the analytics group of EPNOE, which is working on standardization of polysaccharide analysis.

Talk 1: SEC and chitosans – Is it love at first sight or should they just be friends?

This talk focuses on the practical challenges of obtaining reliable and comparable SEC results for chitosan. It highlights critical method parameters, common sources of variability and specific considerations when analyzing chitosans across a broad molecular weight range.

Talk 2: Chitosan regulatory aspects in pharmaceuticals and medical devices

Lecture gives a basic overview of the regulatory frameworks relevant to chitosan in pharmaceutical and medical device applications. It explains the role and scope of ISO 13485, EU-GMP requirements and pharmacopeial standards, and highlights how these frameworks differ and where they become relevant for research and development.

Talk 3: Do three batches prove a process? A regulatory view on validation and process understanding

This presentation highlights why testing only a few chitosan batches may not be sufficient to demonstrate robust product performance. It discusses the importance of including chitosans with different relevant material characteristics during research and development in order to understand variability, define meaningful specifications and establish a reliable design space for the final product.

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